

REMARKS

Entry of this response and reconsideration of the above-referenced application is respectfully requested. Claims 17-19 are pending in the application. Various rejections have been made under 35 U.S.C. § 102 and 35 U.S.C. §103. The rejections will be discussed in the order presented in the Office Action. In light of the discussion below, it is believed that all rejections have been overcome.

I. Rejections under 35 U.S.C. § 102(b)

Claim 17 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,632,772 to Alcime et al.

A. The Present Invention.

The present invention as recited in claim 17 relates to an expandable device for delivery into a blood vessel carrying blood that includes an expandable support frame having first and second end portions, a porous polymer sleeve having inner and outer surfaces, and a coating of a cell adhesion protein carried on and attached to at least one of the inner and outer surfaces of the polymer sleeve for enhancing endothelial cell growth on the polymer sleeve.

B. Cited Document Relating to Anticipation Rejection

Alcime et al. relate to an endothelial graft which is both expandable and supportive and is provided in a form suitable for use in a branched blood vessel location.

C. Legal Standard for Anticipation

According to the Manual of Patent Examining Procedure (MPEP) § 2131, Eighth Edition, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”.

C1. Analysis relating to rejection under 35 U.S.C. § 102(b)

Alcime et al. is relied on for disclosing an expandable support having first and second end portions, a porous polymer sleeve having inner and outer surfaces, and a coating of a cell adhesion peptide carried on and attached to at least one of the inner

and outer surfaces of the polymer sleeve for enhancing endothelial cell growth on the polymer sleeve. Column 13, lines 56-61, is specifically relied on for teaching the coating of a cell adhesion peptide. Column 13, lines 56-61, recites "[t]he surface treatments can also provide for the elution or immobilization of drugs such as heparin, antiplatelet agents, antiplatelet-derived growth factors, antibiotics, steroids, and the like. Additionally, the coating and/or liner can be loaded with drugs such as those discussed herein, as well as lytic agents in order to provide local drug therapy." The Examiner asserts that the "surface treatment" taught by Alcime et al. in column 13, lines 56-60, is a coating and that applicants alleges Alcime et al. or Brown do not disclose, e.g., a "coating".

Applicants actually previously asserted and reiterate that Alcime et al. do not teach or suggest a "coating...for enhancing endothelial cell growth." There is no teaching or suggestion that the drugs recited by Alcime et al. enhance endothelial cell growth.

Additionally, applicants point out that Alcime et al. can also not anticipate the subject invention through inherency because "[a] claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possibly present." *Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1186, 1192, 68 U.S.P.Q.2d 1186 (Fed. Cir. 2003). Applicants respectfully submit that the "coating...for enhancing endothelial cell growth" of the subject invention is not taught or suggested in Alcime et al. and is also not "necessarily present" in that reference. *Akamai Technologies, supra*.

Withdrawal of the rejection of claim 17 under 35 U.S.C. § 102(b) over Alcime et al. is respectfully requested.

II. Rejections under 35 U.S.C. § 103(a)

Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Alcime et al. in view of U.S. Patent No. 5,958,428 to Bhatnagar.

Claim 19 stands rejected under 35 U.S.C. § 103(a) over Alcime et al. in view of U.S. Patent No. 6,071,305 to Brown et al. and U.S. Patent No. 5,958,428 to Bhatnagar.

A. The Cited Documents

Brown et al. teach a directional drug delivery stent which includes an elongated or tubular member having a cavity containing a biologically active agent.

Bhatnagar teach composites that include a biomaterial having compounds thereon with enhanced cell binding with respect to collagen.

Alcime et al. has been previously discussed in section I above.

B. Legal Determination of Obviousness

In order to establish a *prima facie* case of obviousness there must be, *inter alia*, "some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." Manual of Patent Examining Procedure (MPEP) § 2143; See also *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1446 (Fed. Cir. 1992). Additionally, in order to establish a *prima facie* case of obviousness the Examiner must, *inter alia*, provide a prior art reference (or references when combined) that teaches or suggests all the claim limitations. Manual of Patent Examining Procedure (MPEP) § 2143, Eighth Edition. Under these standards as discussed below, the Examiner has not made a *prima facie* case of obviousness.

Furthermore, "a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered." *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F2d 443, 230 USPQ 416 (Fed. Cir. 1986).

In addition, "it is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne can not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992) citing *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988). "It is impermissible ...simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps." *In re Gorman*, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991).

C. Rejection of claim 18 over Alcime et al. in view of Bhatnagar

The Examiner relies on Alcime et al. for allegedly teaching a product recited in claim 18 and that the stent of Alcime et al. is made of metal. Bhatnagar is relied on for allegedly disclosing use of spacer arms to facilitate binding of peptides to a substrate. The Examiner concludes it would have been obvious to provide spacers/linkers as taught by Bhatnagar in order to link the peptides to the metallic Alcime et al. substrate, asserting that this is a well known and conventional means of attaching biomolecules to a substrate.

Applicant first notes that Alcime et al., whose teaching has been previously described in sections I.B and I.C1 above, do not teach or suggest the expandable device recited in pending claim 17 (upon which claim 18 depends and which therefore includes all of the claim limitations of claim 17) for the same reasons set forth in section I.C1 above.

Claim 18 of the pending application can not be obvious over the art of record because Bhatnagar, either alone or combined with Alcime et al., does not teach each and every element of claim 18. For example, claim 18 of the pending application recites the device of claim 17 that includes (without taking into account any of the process limitations) a plasma deposited layer having functional groups that have covalently attached thereto multifunctional linkers/spacers to covalently bind a cell adhesion peptide. Such a plasma deposited layer is not taught or suggested in either Alcime et al. or Bhatnagar. As the cited references alone or combined do not contain each and every claim limitation present in claim 18, claim 18 can not be obvious over this combination of references. Withdrawal of the rejection of claim 18 under 35 U.S.C. § 103(a) over Alcime et al. in view of Bhatnagar is respectfully requested.

D. Rejection of claim 19 over Alcime et al. in view of Brown et al. and further in view of Bhatnagar

Alcime et al. is relied on for allegedly disclosing the invention as claimed. Brown et al. is relied on for allegedly teaching the use of therapeutic drugs such as heparin or collagen on a stent. Bhatnagar is relied on for allegedly teaching the functions of collagen and for allegedly providing synthetic peptides which are allegedly the same as applicant's peptide in SEQ ID NO:1. The Examiner concludes that, because both

Alcime et al. and Brown et al. teach the use of providing a therapeutic drug such as heparin or other drugs on a stent, and Brown teaches the drug may be collagen, it would have been obvious to provide collagen as the therapeutic drug in the Alcime et al. stent with the polymer sleeve. The Examiner further concludes that it would have been obvious to provide a synthetic peptide disclosed by Bhatnagar on the Alcime et al. stent as an alternative to collagen because it would allegedly be desirable to obtain the same therapeutic effect as collagen but without the adverse effects of collagen that are taught by Bhatnagar.

Applicants submit that Brown et al., viewed as a whole, teaches away from the claimed device having a coating, and thus one skilled in the art would have no motivation to combine the cited references. Brown et al. teach a directional drug delivery stent which includes an elongated or tubular member having a cavity containing a biologically active agent. The biologically active agent is described therein as residing in the cavity and is for directional delivery. As one example in column 6, lines 6-9, the device in Brown et al. can have a fluid opening or delivery means for directionally delivering a biologically active agent within the cavity or interior 20. As such, Brown et al. actually teaches away from the claimed device having a coating. One skilled in the art would therefore not be motivated to combine the cited documents. Bhatnagar adds nothing further of significance.

Turning now to the combination of Bhatnagar and Alcime et al., there is no teaching or suggestion to combine these documents. Although Bhatnagar teaches composites that include a biomaterial having compounds thereon with enhanced cell binding with respect to collagen, there is no teaching or suggestion that the graft of Alcime et al. should be modified to include a coating of the peptide described in Bhatnagar because Alcime et al. do not teach or suggest use of a "coating...for enhancing endothelial cell growth" as recited in claim 19 (as claim 19 is dependent on claim 17 and includes all the limitations of claim 17). Any combination of Bhatnagar and Alcime et al. can only come from impermissible hindsight analysis. Applicants are aware that "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a

reconstruction is proper." *In re McLaughlin* 170 USPQ 209, 212 (CCPA 1971). Here, the Examiner's judgment on obviousness necessarily includes knowledge gleaned from applicants' disclosure and is therefore improper. Withdrawal of the rejection of claim 19 under 35 U.S.C. § 103(a) over Alcime et al. in view of Brown et al. and further in view of Bhatnagar is respectfully requested.

III. Conclusion

In view of the above, applicants submit that claims 17-19 are in condition for allowance. Therefore, a Notice of Allowance is respectfully requested.

If the Examiner believes a telephone conference would expedite the prosecution of the present application, the Examiner is encouraged to call the undersigned at (650) 838-4308.

Respectfully submitted,



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